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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,976	07/27/2001	Jyoti Mazumder	POM-12602/29	8577
25006	7590	09/06/2006	EXAMINER	
GIFFORD, KRASS, GROH, SPRINKLE & CITKOWSKI, P.C PO BOX 7021 TROY, MI 48007-7021			KOSOWSKI, ALEXANDER J	
			ART UNIT	PAPER NUMBER
			2125	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,976

Applicant(s)

MAZUMDER ET AL.

Examiner

Alexander J. Kosowski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

- 1) Claims 1 and 3-8 are presented for examination in light of the response filed 6/13/06.

Claim Rejections - 35 USC § 103

- 2) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 3) Claims 1 and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jang et al (U.S. Pat 6,405,095), further in view of Bradbury et al (U.S. PGPUB 2002/0007294), further in view of Koch (U.S. Pat 6,122,564).

Referring to claim 1, Jang teaches a method of fabrication comprising the steps of: receiving digital data from computer tomography or magnetic resonance imaging (col. 15 lines 6-10), constructing a computer-aided design (CAD) file in accordance with the digital data (col. 14 lines 28-62); generating a tool path (col. 15 line 48 though col. 16 line 30); and fabricating a three-dimensional object by depositing material increments along the tool path using a closed-loop direct metal deposition (DMD) process of the type wherein a laser beam is focused onto a workpiece to create a melt pool into which powder is injected (col. 5 line 51 through col. 6 line 8 and col. 16 lines 10-16). However, Jang does not explicitly teach that biomedical implants are being fabricated, that the digital data obtained from CT or MRI scans is related to patient physiology, nor that the size of the increments are controlled through optical monitoring.

Bradbury teaches a system for rapidly prototyping biomedical implants whereby CAD models are created after patient-specific anatomical digital data is gathered, and whereby data is

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converted to manufacturing instructions comprising tools paths to create three-dimensional models (Paragraph 0007, 0016 and 0022).

Koch teaches a method of fabrication utilizing DMD techniques including a melt pool (col. 3 lines 52-53 and col. 5 lines 32-33), whereby an optical monitoring system is utilized as feedback to control the size of deposited material increments (col. 5 lines 54-65).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to receive digital data representative of patient physiology and to fabricate biomedical implants using the method taught by Jang since this would increase the responsiveness of the implant preparation and surgical planning process, would allow customized construction of implants, and would yield superior dimensional matching to a patient's body, which should promote superior tissue and bone ingrowth (Bradbury, Paragraphs 0008 and 0051).

It would also have been obvious to one skilled in the art at the time the invention was made to utilize optical monitoring to control the size of deposited material increments in the method taught by Jang above since optical detection means can be utilized to monitor physical dimensions of deposits, and a feedback controller can utilize this to adjust a laser to thereby control the rate of material deposition (Koch, col. 2 lines 5-9).

Referring to claim 3, Jang teaches the method of claim 1, wherein the materials include one or more metals or ceramics (col. 5 lines 51-58).

Referring to claim 4, Jang teaches the method of claim 1, wherein the materials may include alumina (col. 5 lines 3-6).

Referring to claim 5, Jang teaches the method of claim 1, further including the step of fabricating the object out of different materials using the same DMD process (col. 6 lines 3-8).

Referring to claim 6, Jang teaches the method of claim 5, wherein the different materials include metals, ceramics, or polymers (col. 5 line 51 through col. 6 line 8).

Referring to claim 7, Jang teaches the above. However, Jang does not explicitly teach the step of embedding one or more sensors into the implant for diagnostic or data-acquisition purposes.

Bradbury teaches that sensors may be seeded into implants for diagnostic purposes (Paragraph 0031).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to embed sensors in implants in the method taught above since this would allow a part to be inspected at a later point after fabrication (Bradbury, Paragraph 0031).

Referring to claim 8, Jang teaches the above. However, Jang does not explicitly teach fabricating a scaffold structure suitable to bone ingrowth or ongrowth using the DMD process.

Bradbury teaches fabricating scaffold structures of custom shapes to help bone ingrowth (Paragraphs 0051 and 0082-0083).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to fabricate scaffold structures in the method taught above since this would allow superior dimensional matching to a patient's body which would promote healing (Bradbury, Paragraph 0051).

Response to Arguments

4) Applicants arguments filed 6/13/06 have been considered but are not persuasive.

Applicant argues with reference to claim 1 that the "paragraphs of Bradbury cited...refers only to the system of Bradbury...It does not speak to the combination...Thus, the teachings of

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this paragraph do not carry over beyond the application in which it is contained.” In response, examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Bradbury reference specifically teaches motivations for adding the missing features of claim 1 into the Jang reference. The examiner has established the claim limitations can be found in each reference, and that there is a motivation to combine found in the secondary reference. Therefore, the requirements for an obviousness rejection under 35 U.S.C. 103(a) have been met.

In addition, Examiner notes that applicant appears to be addressing the references individually, rather than as a valid combination under 35 U.S.C. 103(a). Examiner notes that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that there is “no factual evidence...in support of Examiner’s rationale for rejection...these remarks by Bradbury have only to do with Bradbury, and do not provide factual evidence for the proposed combination.” In response, Examiner notes the response above. The motivation given by Bradbury relates directly to the claim limitations that the Bradbury references is utilized to teach in the 35 U.S.C. 103(a) rejection given above.

Applicant argues that with regard to optical monitoring “there is no teaching or suggestion from the prior art in support of the proposed combination with respect to applicants claims”. Examiner disagrees, and notes the rejection of claim 1 above whereby specific motivation for the use of optical monitoring is cited directly from the Koch reference. Therefore, applicants argument that there is no teaching from the prior art is not justified.

Finally, applicant argues again that references to modifying Jang are “specific to the teachings of Bradbury, and do not carry over to the proposed combination”. In response, Examiner again references the response above, and notes that all rejections given under 35 U.S.C. 103(a) in the present office action satisfy the requirements of obvious combinations under 35 U.S.C. 103(a).

Conclusion

5) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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6) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander J Kosowski whose telephone number is 571-272-3744.

The examiner can normally be reached on Monday through Friday, alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard can be reached on 571-272-3749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. In addition, the examiner's RightFAX number is 571-273-3744.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-2100.

Alexander J. Kosowski
Patent Examiner
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A handwritten signature in black ink, appearing to read "L. P. Picard". The signature is fluid and cursive, with the first letters of each name being capitalized and prominent.

LEO PICARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2100